

REMARKS

Claims 1-25 are pending. By this Amendment, claims 1, 5, 9, 13 and 17 are amended. Reconsideration in view of the above amendments and following remarks is respectfully requested.

Applicants appreciate the courtesies extended by the Examiner to Applicant's representatives during the October 11 personal interview. The points discussed during the personal interview are incorporated herein.

**I. CLAIMS 13-15, 17-19 and 21-24 DEFINE PATENTABLE
SUBJECT MATTER PURSUANT TO 35 U.S.C. §102(e)**

The Office Action rejects claims 13-15, 17-19 and 21-24 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 4,834,747 to Gogolewski (hereinafter "Gogolewski"). The rejection is respectfully traversed.

The Office Action asserts that Gogolewski discloses a silicone elastomer shell comprising a substantially homogenous silicone elastomer flexible shell having an interior and opposite exterior surfaces. According to the Office Action, the shell comprises at least one base layer of silicone elastomer and an outer layer of silicone elastomer.

Applicant respectfully disagrees with the Office Action's characterization of Gogolewski. Gogolewski discloses a precipitation method for the manufacture of a biocompatible soft-tissue prosthesis using a co-polymer and a mixed solvent. As described by Gogolewski, the "mixed solvent comprises as a first constituent a fluid which is miscible with the solvent but functions as a precipitating non-solvent with respect to [the] polymer. Furthermore, the mixed solvent comprises a second constituent which is solvent for the polymer." Col. 1, lines 49-53. In order for Gogolewski's precipitation method to work, the solvent constituent must have a higher rate of evaporation than the non-solvent constituent, which acts as the precipitating agent. Col. 1,

lines 57-59. By applying to the desired prosthetic surface a prepared polymer solution in which the amount of saturated polymer is at or near its precipitation point, Gogolewski teaches that evaporation of the more volatile solvent will cause precipitation of the polymer to form the desired coating the prosthetic surface. Thus, in contrast to Applicant's particle based process, the method disclosed in Gogolewski's is entirely fluid-based.

Applicant respectfully submits, under 37 C.F.R. §1.132, the enclosed Declaration of Mr. Eldon Frisch. As is described in detail in the Declaration, the Applicant's claimed product is not disclosed or suggested by the product of Gogolewski. In particular, the Declaration describes how the process disclosed in Gogolewski produces a material that is compositionally and structurally different than Applicant's claimed invention. The Declaration points out several distinctions between the Gogolewski and Applicant's invention. In particular, the Declaration notes that: Gogolewski and Quaid are directed to different classes of polymers; Gogolewski is directed to the use of polyurethane materials that are not capable of vulcanization; and that the processing of the polyurethane materials in accordance with Gogolewski results in a material with changes in its physical shape, but no changes in its chemical structure and physical properties. In addition, the Declaration notes that the process of Gogolewski is incompatible with silicone elastomer material of Applicant's invention.

The Declaration also points out and illustrates that Applicant's invention is compositionally and structurally different than Gogolewski. The Gogolewski material has a random fiber structure that forms interlocking layers with open spaces formed between the random fibers. The Gogolewski material is porous through and through. The interlocking fiber network of Gogolewski does not have any cell walls and there are no enclosed cells for holding a fluid. In contrast, Applicant's invention provides a single silicone layer having a cellular

structure where the cell walls are completely defined. The Applicant's invention also provides a material having a single unitary construction that is formed through the vulcanization of a silicone elastomer base material with an outer surface of silicone elastomer having a textured surface. Thus, as described in the enclosed Declaration, Gogolewski fails to anticipate Applicant's invention as recited in claims 13-15, 17-19 and 21-24. Therefore, withdrawal of the rejection of claims 13-15, 17-19 and 21-24 under 35 U.S.C. §102 is respectfully requested.

**II. CLAIMS 1-25 DEFINE PATENTABLE
SUBJECT MATTER PURSUANT TO 35 U.S.C. §103**

The Office Action rejects claims 1-25 under 35 U.S.C. 103 as being unpatentable over Gogolewski in view of U.S. Patent No. 4,648,880 to Brauman (hereinafter "Brauman"). The rejection is respectfully traversed.

Brauman appears to be cited merely for teaching the use of a rough textured surface in a soft tissue mammary implant. Brauman does not teach or suggest the subject matter of Applicant's claims, either alone or in combination with Gogolewski. In addition, neither Gogolewski nor Brauman provides the requisite motivation to combine and modify their respective teachings to arrive at Applicant's claimed invention. Therefore, Applicant respectfully submits that claims 1-25 are patentable over the combination of Gogolewski and Brauman. Withdrawal of the rejection of claims 1-25 under 35 U.S.C. §103 is respectfully requested.

CONCLUSION

In view of the foregoing, Applicant respectfully submits that this application is now in condition for allowance. Favorable reconsideration and prompt allowance are earnest solicited. Should the Examiner believe that any thing further is necessary to expedite

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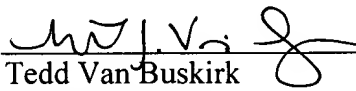
prosecution of this application, the Examiner is invited to contact Applicant's representative at the telephone number listed below.

Please charge any insufficiency of fees or credit any excess to our Deposit Account No. 50-3024. If a fee is requested for an extension of time under 37 C.F.R. §1.6 not accounted for above or otherwise paid to maintain this application in force, such an extension is hereby requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

HOGAN & HARTSON LLP

Date: December 8, 2005


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Attachment:

Declaration Under 37 C.F.R. §1.132 with
enclosures (7 photographs; CV of Mr. Eldon Frisch)